

Application Number 10/698,881  
Amendment responsive to Office Action mailed October 18, 2006

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**REMARKS**

This Amendment is responsive to the Office Action dated October 18, 2006. Applicants have amended claims 4-9 to fix a claim dependency problem. Claim 38 has been amended to address the Examiner's concern regarding intended use. Claim 1 has been amended to address a minor typographical concern unrelated to patentability. Claims 1, 2, 4-11, 18-22, 24, 25 and 27-39 remain pending.

**Preliminary Comment**

In the Office Action, the Examiner indicated that Applicants' last response was not timely since it was *received* at the Patent Office on August 2, 2006 (after the deadline of July 31, 2006). However, the last response was *filed* on July 31, 2006, with a one-month extension of time and a certificate of mailing under 37 C.F.R. 1.8. Applicant paid for the one-month extension of time via check. Accordingly, to the extent that any extension fees have been taken from Applicants' deposit account for a two-month extension, such fees should be refunded as the filing of the response on July 31, 2006 was timely on the one-month extended deadline.

**Claim Objections**

In the Office Action, the Examiner objected to claims 4-9 because of informalities. These claims have now been amended to properly depend upon claim 1.

**Rejection for Obviousness-type Double Patenting:**

The Examiner provisionally rejected claims 1, 3, 5-11, 18, 24, 26, 30, 32 and 38 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-11, 14-16, 22-28, 33-37, 40, 53, 56-58, 61-62, 65-67, 70-73, 78-82, 85-89, and 99-102 of copending Application No. 10/441,784.

Applicants note the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied. In reserving comment at this time, Applicants in no way admit or acquiesce in the propriety of this rejection.

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**Claim Rejections Under 35 U.S.C. § 102 and § 103**

In the Office Action, the Examiner advanced a variety of different rejections. Applicants address the Examiner's rejections of each independent claim in detail below.

***Independent claim 1***

Independent claim 1 recites a method of providing medical therapy to a patient. The method comprises delivering one or more therapeutic stimulation pulses to tissue of a prostate gland via an implantable medical device. In addition, claim 1 requires that the therapeutic stimulation pulses delivered to the tissue of the prostate gland are defined to treat sexual dysfunction by one or more of the following: causing erection, causing ejaculation, preventing ejaculation, preventing premature ejaculation, and causing erection and preventing premature ejaculation

In the previous response, Applicants noted that none of the applied references discloses or suggests stimulation of tissue of the prostate gland specifically for treatment of sexual dysfunction. The Examiner has now advanced two different rejections for claim 1.

First, the Examiner rejected claim 1 (and various dependent claims) as being obvious over Krakovsky (USPN 5,454,840) in view of Whitehurst '294 (USPN 6,901,294). The Examiner stated that Krakovsky teaches electrical stimulation to treat sexual dysfunction, but recognized that Krakovsky does not contemplate any stimulation of prostate tissue. Instead, Krakovsky teaches stimulation of specific nerves (such as the pelvic splanchnic nerves or the pudendal nerves) to treat conditions of impotence.

The Examiner stated that Whitehurst '294 teaches stimulation of prostate tissue to provide a minimally invasive means of reducing prostate volume. The Examiner argued that a person of ordinary skill in the art would have been motivated to modify the techniques of Krakovsky in view of Whitehurst '294 to provide direct stimulation to the prostate tissue for treatment of sexual dysfunction in order to "provide the same benefit of reducing prostate volume with a minimally invasive procedure."

The Examiner's conclusion of obviousness is wrong. A person of ordinary skill in the art would not have been motivated to modify the techniques of Krakovsky in view of Whitehurst '294 to provide direct stimulation to the prostate tissue for treatment of sexual dysfunction. The

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disorders of benign prostatic hyperplasia (BPH) and sexual dysfunction are different disorders. The notion that a person of ordinary skill in the art would have applied the teaching of Whitehurst '294 with regard to prostate tissue stimulation for treatment of BPH in order to address issues of sexual dysfunction addressed by Krakovsky is totally flawed. Nothing in either Krakovsky or Whitehurst '294 suggests that prostate gland stimulation, per Whitehurst '294, would have any benefit for sexual dysfunction disorders addressed by Krakovsky.

Furthermore, if the techniques of Krakovsky were modified to provide prostate gland stimulation, per Whitehurst '294, the teaching of Krakovsky would be compromised. To be sure, Krakovsky teaches stimulation of specific nerves (such as the pelvic splanchnic nerves or the pudendal nerves), and if stimulation were instead provided to the prostate tissue, this would undermine the basic teachings of Krakovsky. For this reason, a person of ordinary skill in the art would have consciously avoided the modifications to Krakovsky in view Whitehurst '294 suggested by the Examiner.

The Examiner's argument that Whitehurst '294 would have motivated this proposed modification to Krakovsky is also flawed. Krakovsky relates to treatment of sexual dysfunction. There is no reason why a person of ordinary skill in the art would want to "provide the same benefit of reducing prostate volume with a minimally invasive procedure" for a patient that suffers from sexual dysfunction. The Examiner has identified nothing that suggests that enlargement of the prostate has any nexus with sexual dysfunction disorders. Furthermore, there is nothing in the prior art of record suggesting that sexual dysfunction has any nexus with enlarged prostate glands. Accordingly, a person of ordinary skill in the art would not have found any motivation to modify the stimulation techniques of Krakovsky that treat sexual dysfunction from the teaching of Whitehurst '294 that treat BHP by reducing prostate volume.

In the Office Action, the Examiner also argued that claim 1 is anticipated by Whitehurst '895 (USPN 6,901,294) or in the alternative obvious over Whitehurst '895 in view of Whitehurst '294. For the anticipation rejection, the Examiner recognized that Whitehurst '895 teaches stimulation of sacral nerves, but provides no suggestion of prostate tissue stimulation to treat sexual dysfunction. The Examiner stated that "it is commonly accepted in the medical art that stimulation of muscle is in fact referring to stimulation of the motor neurons affecting the muscle tissue."

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The Examiner's observations regarding the physiology surrounding muscle stimulation is irrelevant. Whether or not stimulation of muscle is in fact referring to stimulation of the motor neurons affecting that muscle tissue does not change the fact that Whitehurst '895 does not teach or suggest this type of stimulation. In other words, stimulation of the sacral nerves, per Whitehurst '895, is not stimulation of the prostate tissue regardless of physiology surrounding such muscle tissue stimulation.

In the alternative, the Examiner argued that a person of ordinary skill in the art would have considered claim 1 obvious over Whitehurst '895 in view of Whitehurst '294. However, this rejection is flawed for the same reasons advanced above with respect to the rejection of claim 1 based on Krakovsky in view of Whitehurst '294.

Like Krakovsky, Whitehurst '895 fails to teach stimulation of prostate tissue for treatment of sexual dysfunction. Furthermore, as noted above, the teaching of Whitehurst '294 does not concern sexual dysfunction, but relates to treatment of BPH, which is a different disorder than sexual dysfunction.

A person of ordinary skill in the art would not have been motivated to modify the techniques of Whitehurst '895 in view of Whitehurst '294 to provide direct stimulation to the prostate tissue for treatment of sexual dysfunction. The disorders of BPH and sexual dysfunction are distinct and generally unrelated. The notion that a person of ordinary skill in the art would have applied the teaching of Whitehurst '294 with regard to prostate tissue stimulation for treatment of BPH in order to address issues of sexual dysfunction is nonsense. Nothing in either Whitehurst '895 or Whitehurst '294 suggests that prostate gland stimulation, per Whitehurst '294, would have any benefit for sexual dysfunction disorders addressed by Whitehurst '895.

Furthermore, as noted above, if the techniques of Whitehurst '895 were modified to provide prostate gland stimulation, per Whitehurst '294, the teaching of Whitehurst '895 would be compromised. To be sure, Whitehurst '895 teaches stimulation of specific areas that do not include prostate tissue stimulation. If the stimulation were instead provided to the prostate tissue, this would contradict the teaching of Whitehurst '895. For this reason, a person of ordinary skill in the art would have consciously avoided the modifications to Whitehurst '895 suggested by the Examiner.

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The Examiner's arguments that Whitehurst '294 would have motivated any modification to Krakovsky or Whitehurst '895 are unsound. Krakovsky and Whitehurst '895 relate to treatment of sexual dysfunction. There is no reason why a person of ordinary skill in the art would want to "provide the same benefit of reducing prostate volume with a minimally invasive procedure" for a patient that suffers from sexual dysfunction. Furthermore, the Examiner has identified nothing that suggests that enlargement of the prostate has any nexus with sexual dysfunction disorders. Accordingly, a person of ordinary skill in the art would have found no motivation to modify the stimulation techniques of Krakovsky or Whitehurst '895 for treating sexual dysfunction with the teaching of Whitehurst '294 for reducing prostate volume in the treatment of BHP.

Allowance of claim 1 and its respective dependent claims is courteously solicited in view of the foregoing comments.

***Independent claims 19, 24, 28 and 33***

Independent claims 19, 24, 28 and 33 all concern prostate gland stimulation to change the fiber structure of the prostate gland. Such techniques may, for example, be useful in treating benign prostatic hyperplasia (BPH). Claims 19 and 33 recite methods of prostate gland stimulations, whereas claims 24 and 28 recite implantable medical devices that perform prostate gland stimulation.

Each of these claims 19, 24, 28 and 33 specifically require a training sequence that defines a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week. According to claims 19, 24, 28 and 33, the second pulse train (which lasts on the order of a week) is delivered after the first pulse train (which also lasts on the order of a week). The second pulse train includes more pulses per unit time than the first pulse train.

Using this technique, the fiber structure of the prostate gland can be changed in a manner that can remedy effects of benign prostatic hyperplasia (BPH). For example, the prostate gland may become more compliant and thereby remedy effects of BPH.

As a preliminary matter, Applicants note that the Examiner's rejections of independent claims 19, 24, 28 and 33 are inconsistent and don't seem to make sense. One page 7 of the

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Office Action, the Examiner rejects independent claims 19 and 33 (and various dependent claims) as being obvious over Krakovsky in view of Whitehurst '294 and Mann (USPN 6,941,171). However, the Examiner does not reject claims 24 or 28 under this heading.

One page 9 of the Office Action, the Examiner rejects independent claims 24 and 28 (and various dependent claims) as being obvious over Krakovsky, but discusses agent pump features, which are not even recited in claims 24 or 28.

On page 10, of the Office Action, the Examiner rejects independent claims 24, 28 and 33 (but not independent claim 19) as being obvious over Whitehurst '294. In this rejection, however, the Examiner fails to address the features of any of these claims, particularly those relating to the deliver of training sequences of pulses. Whitehurst '294 alone clearly lacks several features of claims 19, 24, 28 and 33, and the Examiner's own analysis seems to recognize this fact insofar as the analysis of claims 19 and 33 as being obvious over Krakovsky in view of Whitehurst '294 and Mann specifically cites Mann for features lacking form Krakovsky and Whitehurst.

On page 13 of the Office Action, the Examiner rejects independent claims 19 and 24 (but not independent claims 28 or 33) as being obvious over Whitehurst '895 in view of Mann, or as being obvious over Whitehurst '895 in view Whithurst '294, Mann and Krakovsky. These rejections also include contradictions relative to other rejections, which are explained in greater detail below.

Furthermore, throughout the Examiner's analysis of the different independent claims 19, 24, 28 and 33, the Examiner makes several references to the treatment of sexual dysfunction. Claims 19, 24, 28 and 33, however, are not even concerned with any treatment of sexual dysfunction, but provide for the delivery of training sequences of pulses to the prostate gland, e.g., for treatment of BHP.

In the following paragraphs, Applicants have endeavored to address all of the arguments advanced with the Examiner with respect to claims 19, 24, 28 and 33. To the extent that the Examiner maintains any of these rejections notwithstanding the discussion below, Applicants request clarification from the Examiner regarding the inconsistencies discussed herein.

With regard to the rejections of claims 19-22 and 33-37 as being obvious over Krakovsky in view of Whithurst '294 and Mann, the Examiner made several mistakes. In this rejection, the

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Examiner recognized that neither Krakovsky nor Whithurst '294 teach the delivery of any training sequence of pulses to the prostate. However, the Examiner cited Mann as disclosing this feature with respect to the bladder, and concluded that a person of ordinary skill in the art would have modified Krakovsky in view of Whithurst '294 and Mann.

First, contrary to claims 19, 24, 28 and 33, Mann does not disclose or suggest the delivery of any training sequence that defines a first pulse train and a second pulse train, wherein the second pulse train includes more pulses per unit time than the first pulse train. The Examiner has factually misconstrued the Mann reference in this respect. The cited passages of Mann simply describe stimulation pulses to the bladder, and do not appear to include any discussion of the use of training sequences of pulses to actually change the physical structure of the bladder.

Second, any stimulation to the bladder, per Mann, has no nexus with prostate stimulation required by Applicants' claims 19, 24, 28 and 33. Thus, if a person of ordinary skill in the art were to modify Krakovsky and Whithurst '294 in view of Mann, the result would be some type of dual stimulation to nerves and the bladder, but not stimulation to the prostate gland itself, and certainly not the delivery of a training sequence that defines a first pulse train and a second pulse train, wherein the second pulse train includes more pulses per unit time than the first pulse train.

The Examiner also recognized that these applied references do not disclose or suggest time periods for the first and second pulse trains are on the order of a week, as required by claims 19, 24, 28 and 33. For these features, however, the Examiner stated that the timing of the sequence is a "result effective variable" that a person of ordinary skill in the art would have uncovered with routine skill.

Contrary to the Examiner's statement, however, nothing in the applied prior art teaches that the timing of a training sequence is result effective. Indeed, the applied prior art does not even teach the use of training sequences, much less suggest that the timing can affect the result. The Examiner's statement that training sequences of first and second pulse trains on the order of a week are result effective variables finds absolutely no support from the evidentiary record and appears to be nothing more than the Examiner's conjecture.

It is well-established that a particular parameter must first be recognized as a result-effective variable, i.e., a variable that achieves a recognized result, before the determination of optimization might be characterized as routine experimentation. The applied

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prior art, however, makes no mention of training sequences, much less teach that time periods for the first and second pulse trains are result-effective variables that can affect training results to the prostate gland. The Examiner's statement that training sequences of first and second pulse trains on the order of a week are result effective variables finds absolutely no support from the evidentiary record

With regard to the Examiner's rejection of claims 24, 25 and 27-29 as being obvious over Krakovsky, as noted above, the Examiner appears to be confused. In particular, in this rejection, the Examiner addressed agent pump features that are not even recited in independent claims 24 and 28 or dependent claims 25, 27 or 29.

Furthermore, the Examiner's rejections of claims 24, 25 and 27-29 as being obvious over Krakovsky fail to address the training sequence features of these claims, and contradict the Examiner's rejections of claims 19-22 and 33-37 as being obvious over Krakovsky in view of Whithurst '294 and Mann insofar as the Examiner specifically recognized that neither Krakovsky nor Whithurst '294 teach the delivery of any training sequence of pulses to the prostate. Independent claims 24 and 28 both require these features.

Similarly, the Examiner's rejections of claims 24, 25, 27-29 and 33-37 as being obvious over Whitehurst '294 fail to address the features of these claims, and contradict the Examiner's own statements in the Office Action. In particular, this rejection fails to address the training sequence features of independent claims 24, 28 and 33, and contradicts the Examiner's rejections of claims 19-22 and 33-37 as being obvious over Krakovsky in view of Whithurst '294 and Mann insofar as the Examiner specifically recognized that neither Krakovsky nor Whitehurst '294 teach the delivery of any training sequence of pulses to the prostate.

The Examiner's rejection of claims 4, 19-22, 24-25 and 27 are also clearly flawed with respect to independent claims 19 and 24, which require deliver of training sequence of pulses to the prostate.

First, the Examiner's statement that Krakovsky teaches delivery of training sequences in FIGS. 12 and 13 is factually incorrect. Nothing in Krakovsky, including FIGS. 12 and 13, discloses or suggests any delivery of training sequences to the prostate or elsewhere. FIGS. 12 and 13 show distinct individual stimulations, not any pulse train or any type of training sequence.



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Even if the pulses shown in FIG. 12 and 13 could be considered a sequence, they clearly do not "train" any physiology, and cannot be considered a training sequence.

Furthermore, these pulses shown in FIGS. 12 and 13 are delivered over a period of 5-20 minutes, which is nothing akin to Applicants' claims which require the different pulse trains to be delivered on the order of a week. As explained herein, the Examiner's dismissal of this feature as being a result effective variable is improper as the prior art does not recognize this variable as effecting this result.

Second, the Examiner's analysis of claims 4, 19-22, 24-25 and 27 as being obvious over Whitehurst '895 in view of Mann; or Whitehurst '895 in view of Whitehurst '294, Mann and Krakovsky is in direct contradiction to the Examiner's earlier analysis of claims 19-22 and 33-37 as being obvious over Krakovsky in view of Whitehurst '294 and Mann.

On page 8 of the Office Action, the Examiner cited Mann as teaching the delivery of training sequences, e.g., as "relaxing the fibrous muscle of the bladder." While this conjecture is factually incorrect, as explained above, it is also noteworthy that the Examiner's own analysis on page 14 of the Office Action recognizes that Mann fails to disclose or suggest the delivery of a training sequence that defines first and second pulse trains. Therefore, the Examiner's own analysis contradicts any assertion that Mann teaches any delivery of training sequences.

Finally, the Examiner's additional reliance on statements of "result effective variables" in the analysis of claims 4, 19-22, 24-25 and 27 to address Applicants' claim requirement of pulse trains delivered on the order of a week is improper, both factually and legally.

As explained above, contrary to the Examiner's statements, nothing in any of the applied prior art teaches or suggests that the timing of any training sequence is result effective. Indeed, the applied prior art does not even teach the use of training sequences, much less provide any suggestion that the timing can effect the result. Again, the Examiner's statement that training sequences of first and second pulse trains on the order of a week are result effective variables finds absolutely no support from the evidentiary record and appears to be nothing more than the Examiner's conjecture.

Independent claims 19, 24, 28 and 33 are allowable over the prior art of record.

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**Claims 30 and 38**

Claim 30 recites a system comprising an implantable medical device that delivers stimulation pulses to a prostate gland, and an agent pump that delivers agents to the prostate gland, wherein the implantable medical device and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complementary fashion.

Claim 38 recites an implantable medical device comprising a stimulator that delivers stimulation pulses to a prostate gland, and an agent pump that delivers agents to the prostate gland, wherein the stimulator and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion.

In the Office Action, claims 30 and 38 were rejected under 35 U.S.C. 102(b) as being anticipated by Krakovsky. In addition, claims 30 and 38 were also rejected under 35 U.S.C. 103 as being obvious over Whitehurst '895 in view of Mann; or Whitehurst '895 in view of Whitehurst '294, Mann and Krakovsky.

Applicants again traverse these rejections. Neither in any of the applied references discloses or suggests the delivery of the stimulation pulses to the prostate gland nor the deliver of agents to the prostate gland, much less the delivery of stimulation pulses and agents to the prostrate gland in a complimentary fashion.

As noted above, Krakovsky teaches stimulation of nerves rather than stimulation of the prostate gland, as required by Applicants claims. Furthermore, for drug delivery, Krakovsky teaches the delivery of drugs to a patient's penis, not a patient's prostate gland.

The delivery of drugs to a patient's penis is not the same as the delivery of drugs to a patient's prostate. Furthermore, nothing in Krakovsky teaches any delivery of drugs to a patient's prostate, much less the delivery of stimulation pulses and agents to the prostrate gland in a complimentary fashion.

Claims 30 and 38 specifically require that the implantable medical device and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion. To the extent that the Examiner views this programming as functional language inherently taught by Krakovsky, the Examiner is wrong. A device that is programmed to deliver the stimulation pulses and the agents to the prostate gland in a complementary fashion, is not suggested by a device of Krakovsky, which is not programmed in this manner. The device

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of Krakovsky does not deliver stimulation pulses to the prostate gland (instead delivering pulses to the splanchnic nerves or the pudendal nerves). In addition, the device of Krakovsky does not deliver agents to the prostate gland. Accordingly, the device of Krakovsky is clearly not programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion, as required by claims 30 and 38.

Like other rejections addressed above, the rejection of claims 30 and 38 under the heading that rejected several claims as being obvious over Whitehurst '895 in view of Mann; or Whitehurst '895 in view of Whitehurst '294, Mann and Krakovsky is unclear. With respect to claims 30 and 38, the Examiner referred only to Whitehurst '895 and not the other references applied in this rejection.

However, Whitehurst '895 (like Krakovsky) does not disclose or suggest a device that is programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion, as required by claims 30 and 38. The cited passages of Whitehurst '895, for example, describe the delivery of agents "to the penis and/or its arterial supply," which is not the same as the delivery of agents to the prostate gland, much less the delivery of the stimulation pulses and the agents to the prostate gland in a complimentary fashion, as required by claims 30 and 38.

Claim 38 has been amended to address the Examiner's concern regarding intended use. This claim now specifically requires a stimulator that delivers stimulation pulses to a prostate gland and an agent pump that delivers agents to the prostate gland. Claim 30 already recites these features in a similar manner. Contrary to the Examiner's statements in the Office Action, claim 30 (and amended claim 38) do not claim the apparatus in a manner in which it is intended to be employed. On the contrary, the claims specifically require the features to be employed in the manner claimed. The agent pump specifically delivers agents to the prostate gland, and the stimulator specifically delivers stimulation pulses to a prostate gland. Furthermore, the delivery of stimulation pulses and the agents to the prostate gland occur in a complimentary fashion, which is not disclosed or suggested in the applied prior art.

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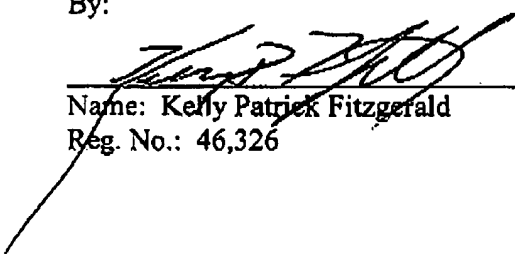
### CONCLUSION

All claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

By:

Dec 27 2007  
SHUMAKER & SIEFFERT, P.A.  
8425 Seasons Parkway, Suite 105  
St. Paul, Minnesota 55125  
Telephone: 651.735.1100  
Facsimile: 651.735.1102

  
Name: Kelly Patrick Fitzgerald  
Reg. No.: 46,326